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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/980,054

02/15/2002

Jean L Lalanne

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11/26/2004

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EXAMINER

DUFFY, PATRICIA ANN

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 11/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,054

Applicant(s)

LALANNE ET AL.

Examiner

Patricia A. Duffy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9-10-04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-46 is/are pending in the application.
- 4a) Of the above claim(s) 34, 35, 45 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30, 32, 33 and 36-44 is/are rejected.
- 7) ☒ Claim(s) 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

The response, declarations and amendment filed 9-10-04 have been entered into the record. Claims 1-29 have been cancelled. Claims 31-46 are pending. Claims 30, 31, 32, 33 and 36-44 are under examination. Claims 34, 35, 45 and 46 are withdrawn from consideration as drawn to non-elected inventions.

The text of Title 35 of the US Code relied upon and not reiterated herein can be found in the previous office action of record.

Lack of Unity

This application contains claims 34, 35, 45 and 46 drawn to an invention nonelected with traverse. Claims 34, 35, 45 and 46 are withdrawn from consideration as drawn to non-elected inventions. The lack of unity deemed final in the last office action. Applicants' petition of the Lack of Unity was denied by the reviewing authority in the Paper mailed 10-12-2004. Applicants are required to cancel the claims in response to the final rejection.

Rejections/Objections Withdrawn

The rejection of the claims under 35 USC 101 is withdrawn in view of the amendments to the claims.

The rejection of the claims under 35 USC 112, second paragraph is withdrawn in view of the cancellation of the claims.

The rejection of the claims under 35 USC 102(b) are withdrawn in view of the amendment of the claims to homologues essential for the viability of a *Candida* species.

Rejections/Objections Maintained

New claims 36-39, 41 and 43 stand rejected under 35 USC 112, first paragraph as failing to comply with the written description requirement for reasons set forth for claims 1-10, 12-16, 27 and 29 in the office action mailed 3-5-04.

Applicants' arguments have been carefully considered but are not persuasive to remove the rejection of record. Applicants argue that the Examiner has failed to give real evidence or reasons why one skilled in the art would not recognize from the disclosure a description of the invention defined by the present claims. The examiner presented a plethora of reasons and cited judicial precedent that clearly indicates that for the now claimed invention, that Applicants were not in possession of a description of protein homologs/variants of SEQ ID NO:12 or the nucleic acids encoding such. There is no description of a single protein variant or a single nucleic acid variant. As set forth previously the courts have held that adequate written description requires more than a statement that it is part of the invention and a reference to a potential method for isolating it. The nucleic acid itself is required. *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.* 18 USPQ2d 1016. The specification fails to provide a representative number of protein or nucleic acid variants of the claimed sequence to indicate that Applicants was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the single disclosed specie of SEQ ID NO:11. The examiner presented a plethora of reasoning and judicial support over five pages of reasoning to establish a *prima facie* case as to why the disclosure of a single nucleic acid species does not provide written description support for the highly variant genus now claimed. Applicants' have chosen not to traverse a single argument or position. Applicants state that the claims are enabled by the specification. This is also not persuasive, enablement is not the issue. Applicants are reminded that *Vas-Cath Inc. v Mahurkar*, 19 USPQ2d 1111 makes it clear that the written description provision of 35 USC 112, is severable from its enablement position (see page 1115). Applicants have confused the written description rejection and the enablement

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rejection on page 6 of their response. Applicants appear to argue that the examiner cited art dated 1976, 1988, 1990 and 1991, this is not so with regard to the written description rejection and this argument has no merit on the bearing of this rejection. Applicants argue the decisions cited in the enablement rejection. These arguments have no merit or bearing on the rejection of record and are addressed in response to the enablement rejection set forth below.

The rejection is maintained for reasons made of record.

New claims 30, 32-33, 36-44 stand rejected under 35 USC 112, first paragraph, because the specification, while being enabled for an isolated polynucleotide consisting of SEQ ID NO:11, vectors comprising an insert consisting of the isolated polynucleotide, host cells comprising the vectors, the specification does not provide enablement for nucleotides having variability as compared to SEQ ID NO:11 or encode variants or homologues the polypeptide of SEQ ID NO:12 for reasons set forth for claims 1-10, 12-16, and 27 in the office action mailed 3-5-04.

Applicants' arguments have been carefully considered but are not persuasive. Applicants have amended the claim to recite homologue. Homologue is deemed any variant of SEQ ID NO:12 or a protein having no sequence identity as compared with SEQ ID NO:12 and can be isolated from any microorganism. Applicants have further amended that the homologue be essential for viability of *Candida*. Applicants argue that the examiner has not developed the enablement rejection from the standpoint of one skilled in the art at the time that the Application was filed and argues that non-1999 references were used to establish the state of the art. The age of the references do not impact the teachings therein. The person in 1999 was well aware of the unpredictability in the art with respect to the issues raised by the examiner. Further, the fact that the art still believed such is clearly supported by the later references cited (1994, 1996 and 1997) that the skilled artisan would still believe these findings at the time that the invention was made.

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Applicants argue that the field of biotech has moved on since these references and the legal decisions were published. Assertions that the "field" of biotechnology can enable the invention are not persuasive. It is the application that must enable the full scope of the invention, not the field of biotechnology. The field of randomly changing amino acids and conserving function is unpredictable and was clearly established for the record. The fact that the same principles were held at the time that the invention was made has been established. Applicants state that the disclosure of a single species may provide adequate written description when the species disclosed is representative of the genus. The disclosed species of SEQ ID NO:11 is representative of a nucleic acid encoding the polypeptide of SEQ ID NO:12. The disclosed sequence of SEQ ID NO:11 is not representative of homologues of undefined structure and unassayable function. Further, as previously set forth the specification does not teach how to use the protein. While the nucleic acid can be used to detect the microorganism, the specification does not teach how to use the protein for all the reasons previously made of record and not traversed.

The rejection is maintained for all the reasons made of record.

Claim 44 stands rejected under first paragraph, as failing to comply with the enablement requirement is maintained for reasons made of record in the previous office action mailed 3-5-04 for the following reason.

The following provision was not provided in the response. "If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by Applicants or assignees or a statement by an attorney of record who has authority and control over the conditions of the deposit over his or her signature and registration number..... that *all restriction upon public access to the deposit will be irrevocably removed upon the grant of a patent and that the deposit will be replaced if the viable samples cannot be dispensed by the depository is required.*" This requirement is necessary when

deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

New Rejections/Objections Necessitated by Amendment

Claim Objections

Claim 36 is objected to because of the following informalities: The claim depends from a non-elected claim. Appropriate correction is required.

Claims 36, 41 and 43 is rejected under 35 USC 102(b) as being anticipated by Alfonso Mendoza et al (*Gene* 229(1-2):183-191, March 18, 1999).

Mendoza et al teach translation elongation factor 2 is encoded by a single "essential" gene in *Candida albicans* and expression of this locus is "essential for vegetative growth". The function of "essential for vegetative growth" appears to be a homologue of the claimed nucleic acid encoding the polypeptide. Applicants describe the homologs and variants as "indispensable for the survival and multiplication of the cells" (see specification page 2, lines 30-32). As such the polynucleotide encoding elongation factor 2, taught by the art as essential for vegetative growth (i.e. multiplication of cells) is by Applicants definition a homologue. Mendoza et al teach that the gene is required for viability (page 188, column 2, lines 9-12). Mendoza et al teach that a plasmid carrying the *C. albicans* gene YEplac112 (TRP1) was used to transform a double disrupt ant of the elongation factor 2 genes of *S. cerevisiae* and expression of the *Candida* gene provided elongation factor 2 activity and provided for viability and growth (i.e. colonies; see page 188-189 section 3.5.1) Mendoza et al teach a homolog required for viability and growth, an expression vector, and host cell comprising the expression vector.

Allowable Subject Matter

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The following claims are currently allowable.

Claim A. An isolated polynucleotide consisting of the nucleic acid sequence as set forth in SEQ ID NO:11.

Claim B. The isolated polynucleotide of claim 1, wherein the nucleic acids sequence is DNA.

Claim C. The isolated polynucleotide of claim 1, wherein the nucleic acid sequence is RNA.

Claim D. An isolated vector comprising as the insert, the isolated polynucleotide of claim A.

Claim E. An isolated host cell comprising the vector of claim D.

Status of the Claims

Claims 30, 32-33, 36-44 are rejected. Claim 31 is objected to as depending from a rejected base claim. Claims 34, 35, 45 and 46 are withdrawn from consideration as being drawn to non-elected inventions.

Conclusion

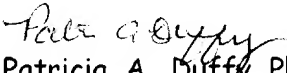
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-

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0855. The examiner can normally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Patricia A. Duffy, Ph.D.

Primary Examiner

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